

§ 807.41 Identification of importers and persons who import or offer for import.

(a) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of any importer (defined in § 807.3(x)) of the establishment's devices that is known to the foreign establishment. The foreign establishment must also specify which of the establishment's listed products each importer receives from the foreign establishment.

(b) Upon initial registration, annually, and at the time of any changes, each foreign establishment required to register and list as provided in § 807.40(a) must, using the FDA electronic device registration and listing system, submit the name, address, telephone and fax numbers, email address, and registration number, if any has been assigned, of each person who imports or offers for import the establishment's devices into the United States. The term "person who imports or offers for import," which is defined in § 807.3(y), includes agents, brokers, or other parties used by the foreign establishment to facilitate the import of its device into the United States.

(c) For each individual or organization identified by the foreign establishment under paragraphs (a) and (b) of this section, the foreign establishment must submit to FDA electronically the current FDA premarket submission number and any other identifying information that is known to the establishment for each device being imported or offered for import by the named individuals or organizations.

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Subpart D—Exemptions

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions

of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5) of the act, that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (d), (e), (f), and (i) of this section are limited to those classes of persons located in any State as defined in section 201(a)(1) of the act.

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.

(b) A manufacturer of devices to be used solely for veterinary purposes.

(c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.

(d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

(e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating "distributed by" or "manufactured for" followed by the name of the pharmacy.

(f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

(g) [Reserved]

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical